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Mr Arthur Neal, Director, Program Administration  
National Organic Program  
USDA-AMS-TMP-NOP  
**1400 Independence Ave., SW.**  
**Room 4008**  
So. Ag Stop 0268  
Washington, DC 20250

**Via E-mail: [National.List@usda.gov](mailto:National.List@usda.gov)**

16 August 2005

Ref: USDA, Agricultural Marketing Service Docket Number TM-04-07 concerning 7 CFR Part 205, National Organic Program Sunset Review process.

Dear Mr Neal,

Jungbunzlauer is a manufacturer of citric acid, citrates, glucono-delta-lactone, and xanthan gum. Jungbunzlauer takes this opportunity to make comments on the Sunset Review of the 2002 National List.

All above mentioned Jungbunzlauer products are on the current National list for Organic products. Since citric acid, citrates and xanthan gum were already commented by industry associations like ECAMA and BIOPOLYMER International Jungbunzlauer would like to focus on glucono-delta-lactone in this letter.

Jungbunzlauer herewith requests the continuance of glucono-delta-lactone on the National List. Jungbunzlauer has provided glucono-delta-lactone to our US customers for their organic product formulations like organic tofu, organic feta cheese, organic mozzarella type cheese, and other organic products.

Exerpt from the ACT.

**§ 205.605 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as “organic” or “made with organic (specified ingredients or food groups(s))”**

**(a) Nonsynthetics allowed:**

**Glucono delta-lactone**

#### Additional Details:

Glucono-1,5-lactone or GdL is a neutral cyclic ester of gluconic acid formed by the removal of water. It is produced by an aerobic oxidative fermentation of glucose. Jungbunzlauer recommends that Glucono delta-lactone remains on the list as per the original evaluation by the NOSB, because Glucono delta-lactone is:

- (1) Not harmful to human health or the environment
- (2) Necessary because of the unavailability of alternatives
- (3) Consistent and compatible with organic practices

Substantial safety and toxicology data exists with JECFA and US FDA Glucono delta-lactone is not harmful to human health or the environment.

Glucono delta-lactone is used as mild acidifier, pH regulator and stabiliser by formulators of various organic products.

Evaluation criteria according to Federal Register / Vol. 70, No. 116 / Friday, June 17, 2005 / Proposed Rules 35181 (Appendix):

#### **CATEGORY 1 - No adverse impacts on humans or the environment**

- Glucono delta-lactone does not contribute any adverse impact to the environment or humans either during production or end-use. During the manufacturing processes, any waste will be discharged to the municipal sewage treatment plant and will be present in only trace amounts.
- There is no significant impact on the environment. Glucono delta-lactone is easily degraded by micro organisms found in the water and soil since Glucono delta-lactone, respectively, gluconic acid, can be found in nature (e.g. plants, honey, wine). Therefore, it does not persist in the environment. Any waste materials will be composted, sent to land fills or treated in wastewater treatment plants. These actions will not result in an adverse effect on the environment.
- Glucono delta-lactone is not on the list, nor does it contain inerts from list 1, 2 or 3.
- There is no potential for detrimental chemical interaction with other materials used.
- There are no adverse biological and chemical interactions in agro-eco-systems.
- There are no detrimental physiological effects on soil organisms, crops, or livestock.
- There is no toxic or other adverse action of the material or and there are no breakdown products.
- There is no undesirable persistence or concentration of the material or breakdown products in the environment.
- There are no harmful effects on human health.

In Europe Glucono delta-lactone is listed as a generally permitted food additive (E 575) and may be added to all foodstuffs, following the "quantum satis" principle, as long as no special regulation restricts the use. The US Food and Drug Administration (FDA) assigned Glucono delta-lactone the "generally recognised as safe" (GRAS) status and permitted its use as a direct human food ingredient without limitation other than current good manufacturing practice (21 CFR Ch. I §184.1318).

Please find attached summary on toxicological and ecological data on Glucono delta-lactone .

**CATEGORY 2 - Substances are essential for organic production.**

Glucono delta-lactone is an especially mild acidifier that allows a slow continuous acidifying process which is essential e.g. for the production of certain organic foods like tofu, cheeses (mozzarella type, feta type, cottage cheese type), doughs, sausages and other meat products.

Further, Glucono delta-lactone is used as mild acidifier in products where the sharp tart taste of e.g. citric acid is not desired, e.g. in meat and seafood products.

**CATEGORY 3 - Substances are compatible with organic production practices**

Glucono delta-lactone is listed at § 205.605

Glucono delta-lactone does not contain the synthetic ingredients in the following categories:

- copper and sulfur compounds
- toxins derived from bacteria
- pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals
- livestock parasiticides and medicines
- production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners

Yours sincerely,

Thomas West

Technical Service Manager  
Jungbunzlauer Inc.

Attachment: